Application/Control Number: 08/228,926

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### DETAILED ACTION

## Inventorship

In view of the papers filed 11/17/2008, the inventorship in this nonprovisional application has been changed by the deletion of Dennis Panicali.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

### Response to Amendment and Arguments

In response to the removal of Panicali as an inventor, the double patenting rejections over patents 5727324, 5614404, 5093258, and 6699475 are withdrawn.

With the cancellation of claim 52, the rejection of claim 52 under 35 U.S.C. 102(b) is moot.

On reconsideration, support for claims 33 and 34 is seen in application 06/334,456 (issued as patent 4769330). Therefore the rejection of these claims under 35 U.S.C. 102(e) is withdrawn.

## Double Patenting

In response to the removal of Panicali as an inventor, the double patenting rejections over patents 5727324, 5614404, 5093258, and 6699475 are withdrawn.

Claim 53 remains rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6632438. In the MPEP, there is a discussion of the conditions for one-way versus two-way double patenting analysis and the supporting case law, in section 804 (II)(B)(1)(b), pages 800-

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22 to 800-24 (Rev 5, Aug 2006, which is still current in the Revision 7 of the 8th edition dated July 2008). The key issue for one-way versus two-way analysis is which party controls the prosecution such that a later-filed application issues first. For claim 33-40, the Patent Office controlled the rate of prosecution, because the claims to this subject matter were pending during interference proceedings which imposed administrative delay. However, claim 53 is not drawn to the same invention as claims 33-40. The subject matter of claim 53 was not presented for examination at the same time as claims 33-40. The subject matter of claim 53 was not claimed until after the issue of patent 6632438. For claim 53, applicants controlled the rate of prosecution, by choosing to wait many years before presenting a claim to this subject matter. "...where, through no fault of the applicant, the claims in a later filed application issue first, an obviousness-type double patenting rejection is improper, in the absence of a two-way obviousness determination, because the applicant does not have complete control over the rate of progress of a patent application through the Office. In re Braat, 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir. 1991)." For claim 53, the Office is not responsible for the delay in filing a claim to the subject matter until after the issuance of 6632438. Therefore, it is maintained that a one-way analysis is appropriate, and the rejection is maintained.

# Claim Rejections - 35 USC § 102

On further consideration of claim 53, a new grounds of rejection is made here based on a more careful construction of this claim. Claim 53 calls for DNA not naturally occurring in vaccinia. flanked by DNA sequences homologous with portions of a

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nonessential region of the vaccinia genome. The claim does not put any minimum size limitations or functional limitations or extent-of-homology limitations on the homologous portions. Therefore, it reads on any DNA, not native to vaccinia, which has two regions with a tiny degree of homology to a vaccinia nonessential region.

Claim 53 is rejected under 35 U.S.C. 102(b) as being anticipated by Bolivar et al, as evidenced by the attached sequence alignment. Bolivar teaches the plasmid pBR322, which certainly comprises isolated DNA not naturally occurring in vaccinia virus. The attached alignment shows that several small regions of pBR322 are homologous to small portions of the vaccinia virus TK gene. Therefore, the pBR322 DNA meets the claim requirements, since the small portions which are homologous flank sequence which is not naturally occurring in vaccinia. This rejection could be obviated by amendment of the claim to require that the portions are sufficient for homologous recombination to introduce the isolated DNA into the vaccinia genome.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher whose telephone number is 571-272-0906. The examiner can normally be reached on varying dates and times; please leave a message.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Mary E Mosher/ Primary Examiner, Art Unit 1648

2/27/09